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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,574	04/23/2001	Marston Manthorpe	1530.0180002/EKS/EJH	1437

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/839,574	MANTHORPE	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *358-417* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *358-417* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/25/03 has been entered.

Claims 1-357 have been canceled as requested over the course of prosecution. Claims 358-417 were entered as requested and are under consideration in this Office Action.

All claims are free of the prior art, so the requirement for election of species, set forth in Paper No. 6, mailed 2/20/02, is withdrawn.

A request to add inventors under 37 CFR 1.48c was received and entered on 9/11/03. Jennifer Meek has been added as an inventor.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 361-379, 392-395, 401, 411-417 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 361-379 are indefinite because, they recite molecular weights but fail to recite units in which the molecular weight is measured.

Claim 371 is indefinite because the it is unclear what is intended by "4% a poloxamer". Insertion of "(w/v) of" after "4%" and before "a" is suggested.

Claims 392-395 are indefinite because it is unclear what is intended by "analogs and derivatives". These claims recite the phrase "fragments, analogs, and derivatives thereof." It is clear what is meant by "fragments", however since "fragments" is an alternative to "analogs" and "derivatives", it is clear that these terms do not embrace fragments and must mean something else. These terms are not defined by the claims or specification and have no single art-recognized meaning, so one of skill in the art cannot know what scope Applicant intends the claims to embrace.

Claim 401 is indefinite because it recites "spinal canal in spinal cord". This inverts the relationship between the spinal canal and the spinal cord because the spinal cord must be in the spinal canal, and not vice versa. Deletion of the word "in" and substitution of the words "surrounding a" is suggested.

Claims 411-417 are confusing because while drawn to a composition, they recite method steps that relate to the use of a composition, but not to a process of making the composition. As a result it is unclear what compositions is being claimed. Deletion of

the phrase "administering into a tissue or cavity of said vertebrate a composition comprising".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 392-395 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 392-395 recite Markush groups comprising various polypeptides, and each claim concludes with the phrase "fragments, analogs, or derivatives thereof." As discussed above, the scope of "fragments" is clear, and it is considered to be adequately described. However, the scopes of "analogs" and "derivatives" are unclear because these terms are not defined by the specification. The claims require the analogs or derivatives to be either "therapeutically active" (claims 392 and 394), "immunogenic" (claim 393), or "immunomodulatory" (claim 395).

The written description requirement for genus claims may be satisfied by sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics,

i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

In this case the specification does not describe by structure or reduce to practice any derivatives or analogs. Further, the specification fails to provide any relevant identifying characteristics such as known or disclosed correlation between a structure that is required for the recited therapeutic, immunogenic or immunomodulatory functions. Based on this disclosure, one of skill in the art could not conclude that Applicant was in possession of the claimed genus at the time of fling.

Enablement

Claims 358-417 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of and compositions for delivering a polypeptide into a vertebrate wherein the compositions and methods comprise about 1 ng to about 30 mg of mRNA, RNA virus, or DNA in aqueous solution wherein the RNA virus or DNA comprises a sequence encoding a polypeptide operably associated with transcription control elements, does not reasonably provide enablement for methods of and compositions for delivering a polypeptide into a vertebrate by delivery of an RNA virus or DNA that encodes the polypeptide, but lacks transcriptional control sequences in operable association with the polypeptide-encoding sequence. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims recite in part (a) about 1 ng to about 30 mg of a polynucleotide in aqueous solution which operably encodes a polypeptide upon delivery to vertebrate cells in vivo. In view of the specification at paragraphs 120, 125, and 126, the scope of "polynucleotide" includes DNA and RNA, and the scope of RNA includes mRNA and integrating and non-integrating RNA viruses. The specification while defining the phrase "operably associated" at paragraph 128, does not define the phrase "operably encodes". So, "operably encodes" has been given its broadest reasonable interpretation, and is considered to embrace any RNA virus or DNA that encodes a polypeptide, regardless of whether or not it is associated with a promoter. It is clear that one of skill in the art cannot practice the claimed invention of delivering a polypeptide into a vertebrate by delivering an RNA virus or DNA encoding that polypeptide unless the polynucleotide open reading frame is, or becomes, operably associated with transcription control elements. While those of skill in the art appreciate that a promoterless open reading frame may be expressed in vivo by chromosomal integration downstream of endogenous transcription control elements, the instant specification teaches at paragraphs 130 and 131 that non-integrating DNAs are preferred, and does not contemplate the use of the invention to integrate any open reading frame downstream of an endogenous promoter. For example, the specification does not teach how to induce an integrating RNA virus to insert downstream of a promoter such that one can predictably obtain transcription of the desired polypeptide. The specification

contemplates expression of polypeptide encoding sequences from non-mRNA platforms only by operable association with transcription control elements.

Because one cannot express a polypeptide from a DNA without transcription into an RNA message, because the specification teaches against the use of integrating DNAs that might associate with an endogenous promoter, and because the specification does not teach how to reproducibly and predictably achieve RNA virus integration proximal to a promoter that can drive transcription of a promoterless open reading frame in the RNA virus, one of skill in the art would have to perform undue experimentation in order to practice the invention commensurate in scope with the claims.

This rejection can be overcome by amending part (a) of the claims to read:

"(a) about 1 ng to about 30 mg of a polynucleotide in aqueous solution wherein the polynucleotide is capable of expressing a polypeptide upon delivery to vertebrate cells".

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 571-272-0564.

Richard Schnizer, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER